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Application No. / Patent No. 97 904 958.2 - 2305 / 0888093 / 22071 EP 1 17.12.2003

Proprietor

EVYSIO MEDICAL DEVICES ULC

Decision revoking the European Patent (Article 102(1), (3) EPC)

The Opposition Division - at the oral proceedings dated 21.11.2003 - has decided:

European Patent No. EP-B- 0888093 is revoked.

The reasons for the decision are enclosed.

Possibility of appeal

This decision is open to appeal. Attention is drawn to the attached text of Articles 106 to 108 EPC.

Opposition Division:

Chairman: 2nd Examiner: 1st Examiner: FONTENAY P H E RUFF C C HOOPER M C



Neresheimer, E Formalities Officer Tel. No.: +49 89 2399-2913

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Enclosure(s):

15 page(s) reasons for the decision (Form 2916) Wording of Articles 106 - 108 (Form 2019)

[] Minutes of oral proceedings

to EPO postal service: 12.12.03

Europäisches Patentamt GD2-Einspruch

European Patent Office DG2 - Opposition

Office européen des brevets DG2 - Opposition

Application No.:

97 904 958.2

Patent No.:

EP-B-0888093

A copy of the communication (communication/decision/minutes) was printed for and notified to each of the following representatives/parties:

Plougmann & Vingtoft AS Sundkrogsgade 9, P.O. Box 831 2100 Copenhagen O DANEMARK

01 McLeish, Nicholas Alistair Maxwell Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT ROYAUME-UNI



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Facts and Submissions

European Patent 0 888 093, which derived from European Patent Application 97904958.2, which itself derived from International Application PCT/CA97/00151 (filed on 05th March 1997), was granted on 18th July 2001 (Bulletin 2001/29). The application claimed priority dates of 05th March 1996, 03rd May 1996, 17th September 1996 and 10th December 1996. The patent proprietor is EVYSIO Medical Devices ULC, Vancouver (CA).

Against this patent an opposition was filed by Guidant Corporation of Indianapolis 2. (US) with letter dated 16th April 2002. In this letter, the applicant requested the revocation of the present patent as a whole on the grounds of Articles 100(c) EPC as the subject-matter of the patent was said to extend beyond the application as filed. Furthermore, another ground for opposition was Article 100(a) EPC, as the subject-matter of the patent was alleged to lack novelty (Articles 54(2) and (3) EPC) and inventive step (Article 56 EPC), in view of documents

D1:

WO-A-97/33532

D2:

WO-A-96/03092

D3:

US-A-5 449 373

D4:

US-A-5 104 404

D5:

EP-A-0 709 067

D6:

US-A-5 607 442

D7:

EP-A-0 669 114

D8:

WO-A-98/33546

Additionally, the US application 08/615 697, which is one of the priority documents of D1, was filed. This document is assigned the number D9.

Oral proceedings were requested as an auxiliary measure.

In a letter of reply dated 2nd December 2002 the proprietor filed arguments regarding all grounds of opposition and requested that the opposition be rejected and the patent be maintained as granted. Oral proceedings were also requested as an auxiliary measure.



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- In the summons to attend oral proceedings dated 21st February 2003 the opposition division indicated in a preliminary, non-binding opinion, that the patent appeared to fulfil the requirements of Articles 54, 56 and 123(2) EPC. A final date for submitting further facts and requests was fixed as one month prior to the oral proceedings.
- 5. In a letter dated 21st October 2003, the patent proprietor indicated that no further requests were to be filed at this stage.
- 6. In a letter also dated 21st October 2003, the opponent filed further arguments as to why the subject-matter of the patent did not comply with the requirements of Article 123(2) EPC.
- 7. Oral proceedings were held on the 21st November 2003. During these oral proceedings the proprietor filed an auxiliary request. The requests of the proprietor can therefore be summed up as follows:

Main request: Rejection of the opposition and maintenance of the patent in unamended form.

Auxiliary request: Maintenance of the patent in amended form, with claim 1 as amended as attached to the minutes of the oral proceedings.

Furthermore, the proprietor requested that Mr. Waugh, additional representative of the opponent, should not be allowed to speak, as Mr. McLeish, the main representative of the opponent, did not have the right to sub-authorise other representatives.

The opponent maintained the request for revocation of the patent in its entirety, on the grounds that the main request contravened Article 123(2) EPC, and that the auxiliary request lacked novelty over D1, Article 54(3) EPC.

8. After due consideration of the parties' submissions the chairman announced the decision that the patent is revoked under Article 102(1) EPC, as the main request contained subject-matter going beyond the application as originally filed, thereby



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contravening Article 123(2) EPC, and the auxiliary request was not novel over D1, Article 54(3) EPC.

II Reasons for the decision

- 1. The opposition is admissible, as the requirements of Articles 99(1) and 100 EPC and of Rules 1(1) and 55 EPC are complied with.
- 2. Permission to grant sub-authorisations
- 2.1. The patentee alleged that the opponent's representative (in this case Mr. McLeish) did not have the right to file sub-authorisations, as there was no explicit permission in the file by the opponent that the representative was allowed to grant such sub-authorisations. Reference was also made to decision T0314/99 and the EPO Official Journal 1991, p. 489. Hence Mr. Waugh, who was supposed to be granted such a sub-authorisation, should not be allowed to speak, as he did not have the authority to represent the opponent.
- 2.2. In reply, the opponent's representative pointed out that it was not necessary to have an explicit authority of the opponent to file sub-authorisations, and that this was common practice at the European Patent Office.
- 2.3. The opposition division has to agree with the opponent. As there is no explicit prohibition by the opponent for the opponent's representative known to the opposition division to file sub-authorisations one has to assume that Mr. McLeish, as a representative of the opponent, is deemed to express his will and is therefore entitled to file sub-authorisations, in so far these relate to persons entitled to be representatives under Article 134 EPC. As Mr. Waugh appears to fulfill the requirements of Article 134(7) EPC, there is no reason not to admit him as a further representative for the opponent. T0314/99 and the EPO Official Journal article do not stand in the way of such a decision. The fact that a power of attorney is no longer requested (EPO Official Journal 1991, p. 489) does not contradict the previous finding.



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- Added subject-matter, Articles 100(c) and 123(2) EPC 3.
- 3.1. "longitudinal"
- The opponent argued that the replacement of the term "disposed substantially 3.1.1. parallel to the longitudinal axis of the stent" with the simple term "longitudinal" introduced subject-matter not present in the originally filed application documents. These terms were not synonymous, as a strut could be "longitudinal" without having to be "disposed substantially parallel to the longitudinal axis of the stent". The dictionary definition of the term "longitudinal" was merely "extending in the direction of the length of a thing; running lengthways" (quoted from "Encyclopedic World Dictionary", Hamlyn, submitted by the patentee) and this was silent as to the exact orientation of the strut. A strut could be seen as running lengthways without being substantially parallel to the longitudinal axis of the stent, see the figure on page 2 of the opponent's letter dated 21st October 2003.

That "disposed substantially parallel to the longitudinal axis of the stent" meant something else than "longitudinal" per se could also be inferred from the original application, where on page 12, line 31 - page 13, line 5 it is stated that "Side walls 35, 40 are substantially parallel to a longitudinal axis 45 of stent 10 and thus side walls 35, 40 may be considered to be longitudinal struts [...]". This indicates that precisely because the side walls are "disposed substantially parallel to the longitudinal axis of the stent", they are to be considered longitudinal. The converse is therefore not necessarily true, i.e. merely because it is a longitudinal strut it is not necessarily parallel to the longitudinal axis of the stent.

3.1.2. In response the patentee stated that the term "disposed substantially parallel to the longitudinal axis of the stent" was indeed a synonym for "longitudinal", and that these terms could therefore be exchanged without infringing Article 123(2) EPC. Furthermore, there was basis for this term in the originally filed documents, see e. g. page 4, lines 11-21. The right-hand figure shown by the opponent in his letter dated 21st October 2003 on page 2 merely had a longitudinal component, but did not show a longitudinal strut as such.



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The opposition division has to agree with the opponent. The application as 3.1.3. originally filed only shows longitudinal struts which are disposed substantially parallel to the longitudinal axis of the stent. Whenever the "longitudinal struts" are described in the application, it is immediately pointed out that these "longitudinal struts" are indeed disposed substantially parallel to the longitudinal axis of the stent. The passages relied upon by the patentee (e. g. page 4, lines 11-21) are no different in this respect, and the figures also only show these struts with one particular orientation. Concerning the argument according to which the term "longitudinal strut" was anyway supported by the cited passages, the opposition division notes that this sentence merely constitutes a definition of the term "longitudinal strut" which indeed departed from the meaning it has in the English language. The opposition division, however, gives the terminology its normal meaning. Should a specific meaning be associated with the term "longitudinal strut", then this definition should have been reproduced in the claim (see Guidelines, C-III, 4.2).

The definition of the term "longitudinal" as "running lengthways" allows for an alignment of a strut such that it is not disposed parallel to the longitudinal axis, but merely has a lengthways component. As long as the major component of the strut is in the lengthways direction of the stent, it can be regarded as a "longitudinal strut", which clearly also entails possible orientations that cannot be regarded as being "disposed substantially parallel to the longitudinal axis of the stent". The arrangement shown by the opponent on page 2 (right-hand figure) of his letter dated 21st October 2003 is precisely such a possibility.

The term "longitudinal" is therefore broader than "disposed substantially parallel to the longitudinal axis of the stent" and not merely a synonymous replacement. This substitution therefore introduces subject-matter going beyond the application as originally filed, and the requirements of Article 123(2) EPC are not complied with.

3.1.4. As the auxiliary request includes the term "disposed substantially parallel to the longitudinal axis of the stent" it is obvious that the auxiliary request does not suffer from this deficiency.



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3.2. "in spaced relation"

3.2.1. The opponent pointed out that there is no explicit textual basis for this term in the originally filed application. Hence one had to rely on the disclosure of the figures to provide a possible basis for the term. However, the figures relied upon by the patentee were figures 8-10 and 12d, e, f and g of the original application, which only ever show devices where the flexure means which are connected to the adjacent rows by two straight sections. The term "in spaced relation" however was not limited to spacing the flexure means by two straight sections, indeed it was possible to envisage the flexure means being spaced from adjacent rows by any form of structure, e. g. by means of two curved sections. Since such a design was never forseen in the original application, it is clear that the introduction of this term introduced subject-matter going beyond the original filing.

Further evidence could be found in the fact that the proprietor had included as claim 10 the precise wording which would describe the longitudinal strut as including the flexure means between two straight sections, hence claim 1 had to be construed as including other embodiments, i. e. where the flexure means was not between two straight sections.

Additionally, the opponent did not see that the function of the spacing of the flexure means from the adjacent rows of intersecting members could be found in the originally filed documents. During the examination of the patent application, the patentee wrote in a letter dated 8th November 1999 that the feature of spacing the arcuate flexure means with respect to the adjacent rows of intersecting members "[...] serves to improve the durability of the stent after deployment." and it "[...] serves to separate and isolate on the one hand the recoil stress forces and on the other hand the pulsed flow stresses to which the stent is subjected after deployment by substantially isolating the latter to the longitudinal struts [...]". The opponent failed to find this function anywhere in the originally filed documents, which do not mention spacing the flexure means at all.

3.2.2. The patentee disputed these claims, and pointed to page 5, lines 7-27, where the flexure means is said to be disposed in the longitudinal strut. Furthermore,



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the flexure means may comprise "at least one lateral section disposed in the longitudinal strut", i. e. the patentee could not see any restriction, be it implicit or explicit, on the nature of the remaining portions of the longitudinal which connect the flexure means to rows of intersection members. Additionally, when the preferred embodiment of the flexure means is described on page 5 in lines 30-32, it is stated that "[...] the remaining portion of the strut is substantially straight". Hence it was possible to have the general term "in spaced relation" in the claims without contravening Article 123(2) EPC, as sufficient basis for this term was to be found in the application as filed.

3.2.3. The opposition division has to agree with the opponent. There is no textual support for the term "in spaced relation", and the passages referred to by the patentee do not help to define such a broad term. It may well be that the application as originally filed did not place any explicit or implicit restriction on the precise shape of the longitudinal strut, but this is not sufficient basis for the definition of the general phrase "in spaced relation", when the application only ever shows a strut in which the flexure means is placed between one or two straight sections, see figures 8-10 and 12. This is even confirmed by the passage on page 5 in lines 30, which again only describes a straight configuration for the parts which do not constitute the flexure means. Furthermore, the opposition division also fails to see that the alleged effect can be found in the originally filed documents and that it had to be described in such broad terms.

The introduction of the term "in spaced relation" therefore introduces subjectmatter going beyond the application as originally filed, and the main request therefore fails to comply with the requirements of Article 123(2) EPC in this respect.

3.2.4. The opposition division however does not see a problem if the wording of claim 10 is included in the independent claim instead of the term "in spaced relation". The wording of claim 10 is clearly shown by the figures 8-10 and 12. Therefore no objection under Article 123(2) EPC needs to be raised against the auxiliary request in this respect, where the patentee chose to do such a substitution.



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3.3. "arcuate"

3.3.1. Here the opponent states that the term "arcuate" was only introduced during the prosecution of the application and that there is again no textual support for this term. By definition, arcuate means "shaped like a bow" or, more generally, "curved". However, "curved" was so general that it included flexure means that were never envisaged by the application as originally filed. Furthermore, if "arcuate" was a synonym for "shaped like a bow", then the sinusoids of figures 8-10 would not be covered, as a sinusoid is not shaped like a bow.

Hence one has to assume that Article 123(2) EPC is not complied with by the introduction of this term.

- 3.3.2. The patentee responded by agreeing that "arcuate" merely meant "curved". However, the various embodiments shown in the application could be regarded as "arcuate", as the claim only specified that an arcuate means should be present, making no further statements as to what the rest of the flexure means looked like. A sinusoid was therefore also covered, as it simply consisted of two bow-shaped arches attached to each other. And even the broad definition of "arcuate" as being "curved" is covered by the application as originally filed, as the various embodiments of figures 8-10 and 12 showed such curved sections.
- 3.3.3. The opposition division considers the term "arcuate" to be synonymous with the term "curved", as this is one definition of the term as given in the extract of the Concise Oxford Dictionary of Current English.

However, no infringement of Article 123(2) EPC is seen by the opposition division by the introduction of this term. The figures 8-10 and 12 (specifically 12d-g), and the corresponding parts of the description, as originally filed, are considered as providing enough basis for the general term "arcuate", as different types of curved sections are shown, be they sinusoidal, S-shaped, bowed, or Ω -shaped.

It is particularly important to note that figure 12 is present to provide a basis for the general term "arcuate". The other figures merely show sinusoidal, or Sshaped, flexure means, and without figure 12 present only this term would have



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been acceptable under 123(2) EPC, as the generality of "arcuate" would not have been given.

3.4. Deletion of figures

- 3.4.1. The opponent objected to the deletion of the figures 12a, 12b, 12c, 12h and 12i. These figures showed non-curved flexure means, and in the description, e.g. page 18, lines 12-14, it is suggested that the advantages of the invention can be achieved with any shape of flexure means. Now that the non-curved flexure means were deleted it was suggested that only curved means can achieve the advantages of the invention. This amounted to subject-matter being included that was not previously present in the originally filed application.
- 3.4.2. The patentee responded by pointing out that this was merely the adaptation of the description to the amended claims, which the patentee was requested to do by the examiner entrusted with the examination of the application.
- 3.4.3. The opposition division also fails to see how such a deletion, which it regards as an adaptation of the description to modified claims, should have introduced further subject-matter. The term "arcuate" was introduced into the claim, where no equivalent term was included previously, and the figures were merely adapted to the changed claim. In fact, the opposition division considers the embodiments corresponding to figures 12d-g to be sufficient to support the term "arcuate", giving said term the meaning it has in the dictionary, i. e. curved. No new teaching was "created" by such a deletion. Therefore no objection regarding Article 123(2) EPC can be raised against this deletion of figures 12a, 12b, 12c, 12h and 12i.
- 3.5. For the reasons set out above the main request is considered as containing subject-matter going beyond the application as originally filed, and therefore the requirements of Article 123(2) EPC are not complied with. However, these deficiencies are remedied in the auxiliary request, and no further objections regarding Article 123(2) and (3) EPC were raised by the opponent, nor are they raised by the opposition division.



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4. Priority

The auxiliary request includes the term "arcuate", which it was decided was not an infringement of Article 123(2) EPC, due to figures 12 and the corresponding parts of the description. These parts however are only part of the international application and do not appear in any of the priority documents. Therefore the claim to priority does not appear to be valid, and the effective date for consideration or prior art is the international filing date, i. e. 5th March 1997. The patentee did not contest this point.

5. Novelty, Articles 100(a) and 54(3) EPC

- 5.1. D1 as prior art under Article 54(3) EPC
- 5.1.1. Document D1 corresponds to international application PCT/US97/03545 and was published on 18th September 1997. It designates, amongst others, AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE. These are the same states that the present patent designated in its international application. The document was supplied to the EPO in one of its official languages and the national fees provided for in Article 22, paragraph 1 or Article 39 paragraph 1 of the Co-operation treaty has been paid. The requirements of Article 158(1) EPC are thus fulfilled. D1 furthermore entered the European Regional Phase with the patent application number 97908050.4. This application claims the priority dates of 13th March 1996 and 7th October 1996 on the basis of US patent applications D9 and 60/028 928 respectively.

Figures 7a-7g and the parts in the description relating to these figures are contained in D9.

5.1.2. The patentee pointed out that D9 was a continuation-in-part of the prior application 60/008 254 and therefore questioned if priority was validly claimed, as D9 might not be the first filing, Article 87(1) EPC, thereby possibly invalidating any claim to priority.

However, this is not the case. The figures 7a-7g and the relevant parts in the description are, in the absence of evidence proving the contrary, included in D9 for the first time, and therefore priority is assumed to be validly claimed.



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- 5.1.3. Therefore the subject-matter in D1, in so far as it is not contained in application 60/008 254, is entitled to the priority date of 13th March 1996. As a consequence, the figures 7a-7g and relevant parts in the description are comprised in the state of art according to Article 54(3) and (4) EPC, in combination with Rule 23a EPC, for all states.
- 5.2. Novelty of the present patent over D1
- 5.2.1. Claim 1 of the auxiliary request reads as follows:

"An unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of rows of intersecting members [...], adjacent rows of intersecting members being interconnected by a series of longitudinal struts substantially parallel to the longitudinal axis [...], the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent; characterised in that each longitudinal strut [...] comprises an arcuate flexure means [...] disposed in the longitudinal strut between a first straight section and a second straight section between adjacent rows of intersecting members [...] to allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts [...] upon flexure of the stent."

- 5.2.2. It is undisputed by both parties that D1 shows a stent comprising a proximal end and a distal end in communication with one another, the tubular wall having a longitudinal axis, and a surface defined by a plurality of rows of intersecting members. Furthermore, the parties seem to agree that longitudinal struts, which include flexure means, are included in this stent and that these struts are substantially parallel to the longitudinal axis.
- 5.2.3. The opponent now states that figure 7a also shows the remaining features, i.e. an unexpanded stent, where adjacent rows of intersecting members are interconnected by a series of longitudinal struts, where the flexure means are arcuate and disposed in the longitudinal strut between a first straight section and a second straight section (see also figure 7b), where the configuration allows for substantial complementary extension and compression of a



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diametrically opposed pair of the longitudinal struts upon flexure of the stent. Furthermore, it was obvious that the surface was porous.

And even if D1 did not show an unexpanded stent but rather an expanded stent, the opponent considered that a person skilled in the art would immediately be able to infer what the unexpanded version was like, and that the flexure means are arcuate in such an unexpanded state too. Additionally, it was pointed out that claim 1 was not limited to balloon-expandable stents, but also covered self-expanding stents, as column 17, lines 7-10 stated "[...] the radially outward force exerted on the stent would be generated within the stent itself".

5.2.4. The patentee disagreed with this interpretation of D1. Figure 7a showed an expanded stent, which therefore did not fall within the scope of claim 1. The description made it clear that the stent shown would only be bent upon deployment to conform to the shape of the vessel. As figure 7a showed a bent configuration it was clear that this stent as shown was in its deployed state, i. e. expanded. Additionally, and perhaps more importantly, for the person skilled in the art it would not be immediately obvious what the unexpanded stent should look like. It was also made clear in the description that the stent was selfexpanding.

And further differences between the subject-matter of claim 1 and D1 include the fact that the flexure means are arcuate, whereas in D1, figures 7a-7g no arcuate flexure means are shown. Arcuate, or curved, flexure means would be those that caused minimal trauma to the vessel wall during deployment.

The patentee also disputed that the surface shown is porous, seeing that something like the flexure means of figure 7c tend to stick out of the surface and therefore the surface could not be described as porous.

And finally, claim 1 specifies that adiacent rows of intersecting members be interconnected with a series longitudinal struts. In D1, however, not all adjacent rows of intersecting members were interconnected by longitudinal struts. The rings 114 in figure 7a did not constitute a single row of intersecting members



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but indeed comprised two rows of intersecting members, which were clearly not linked by longitudinal struts as required.

5.2.5. The opposition division has to agree with the opponent. It is conceded that D1 shows in figure 7a a stent which is expanded, but it is however immediately obvious for the person skilled in the art what shape and form the unexpanded stent would have to assume in order to arrive at an expanded state as shown. All that is necessary is to shrink the various parts in radial and longitudinal directions, something that requires no imagination on the part of the average person skilled in the art. As the flexure means shown in figure 7a are shown in a stretched configuration at the upper end of the figure and in a compressed configuration at the bottom end of the figure it is even obvious what the flexure means must look like in a "relaxed" state, as it must have a shape somewhat intermediate these two extremes.

The patentee did not substantiate the allegation that a person skilled in the art would be unable to deduce the shape of the unexpanded stent from the illustration of figure 7a. As stated, it seems to be a rather simple exercise for any person skilled in the art.

Furthermore, although the wording of claim 1 suggests on a superficial reading that only balloon-expandable stents are meant it is obvious from the description, column 17, lines 7-10, that no such limitation is intended. Therefore it is not of relevance that the stent of D1 is self-expanding, as the claims of the present patent do cover such embodiments too.

Figure 7b, which is described as an alternative to the flexure means of figure 7a, furthermore shows that the flexure means is arcuate and that it is disposed in the longitudinal strut between a first straight section and a second straight section. The flexure means is considered to be arcuate, as arcuate merely meant curved, which the part 118 was considered to be. No further properties could be inferred from the term arcuate, so the reference by the patentee to the reduced possibility of causing trauma by arcuate flexure means is of no importance.



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As to the objection by the patentee that not all adjacent rows are connected by longitudinal struts it is to be said that the opposition division does not agree. The suggestion by the patentee that rings 114 consist of two rows of intersecting members is one way of looking at the figure, but the opposition division considers ring 114 to be a single row of intersecting members, such that all adjacent rows are interconnected in the required manner. As these rows already provide for the porous surface of the stent it is of no importance which of the flexure means shown is actually used, so the reference to figure 7c by the patentee is of no relevance.

It is also pointed out that the required functionality, i.e. that the flexure means allow for substantially complementary extension and compression a diametrically opposed pair of the longitudinal strut upon flexure of the stent, is clearly given in D1, seeing that figure 7a shows just such a case, be it in the expanded or unexpanded state.

- 5.2.6. All features of claim 1 are disclosed in combination in D1. Therefore, the subject-matter of claim 1 of the auxiliary request lacks novelty, Article 54(3) EPC, over the disclosure of D1.
- 6. No further requests were allowed into the proceedings, as the patentee failed to observe the time limit set under Rule 71a EPC. The opposition division did not allow any further requests, as it did not appear possible to file a set of claims which *prima facia* met all outstanding objections and the requirements of the EPC.

The patentee claimed to have a right under Article 113 EPC to file further requests. This is however an erroneous claim. E.g. decision T476/96 makes it clear that the right to be heard, Article 113(1) EPC, required that the facts and evidence relied upon be presented in due time, i. e. early enough for the other side to have the time to examine them properly and draw the necessary conclusions for its defence. Additionally, T97/94 makes it clear that if a time limit is set under Rule 71a(1) EPC, as happened in this case, then it is binding on the parties.



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In this case, one further request was allowed, as the opposition division was of the opinion that the objections raised under Article 123(2) EPC could easily be remedied.

As the two requests on file do not meet the requirements of the EPC the patent 7. is revoked under Article 102(1) EPC.



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Plougmann & Vingtoft A/S Sundkrogsgade 9, P.O. Box 831 2100 Copenhagen O DANEMARK

Application No. / Patent No. 97 904 958.2 - 2305 / 0888093 / 22071 EP 1 17.12.2003

Proprietor
EVYSIO MEDICAL DEVICES ULC

Provision of a copy of the minutes in accordance with Rule 76(4) EPC

The attached copy of the minutes of the oral proceedings is sent to you in accordance with Rule 76(4) EPC.



Neresheimer, E Formalities Officer Tel. No.: +49 89 2399 - 2913

Enclosure(s): Copy of the minutes (Form 2309)

ORAL9, (OREX) coded

Europäisches Patentamt GD2-Einspruch

European Patent Office DG2 - Opposition

Office européen des brevets DG2 - Opposition

Application No.:

97 904 958.2

Patent No.:

EP-B-0888093

A copy of the communication (communication/decision/minutes) was printed for and notified to each of the following representatives/parties:

Plougmann & Vingtoft A/S Sundkrogsgade 9, P.O. Box 831 2100 Copenhagen O DANEMARK

01 McLeish, Nicholas Alistair Maxwell Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT ROYAUME-UNI Europäisches Patentamt GD2 - Einspruch European Patent Office DG2 - Opposition

Office européen des brevets DG2 - Opposition

Application No.:

97 904 958.2

Patent No.:

EP 0888093 B

Minutes of the oral proceedings before the OPPOSITION DIVISION

The proceedings were public.

Proceedings opened on 21.11.2003 at

003 at 9.00 hours

Present as members of the opposition division:

Chairman:

FONTENAY PHE

1st member:

HOOPER M.C.

2nd member:

RUFF C C

Minute writer:

RUFF C C

Present as or for the party or parties:

• For the Proprietor(s): EVYSIO MEDICAL DEVICES ULC

(a) H. R. Andersen, representative G. M. Desrousseaux, representative

(b) O. A. Nassif, Canadian attorney for Evysio Medical Devices ULC

D. R. Ricci, inventor

M. Dalkiaer

• For the Opponent 1: Guidant Corporation

N. A. M. McLeish, A. Waugh, T. L. Kitchen, C. Lehman, C. Taylor, M. A. Morin

The identity of the person/s (as well as, if applicable, that of the witness or witnesses) and, where necessary, the authorisation to represent/authority to act were checked.

Essentials of the discussion and possible relevant statements of the parties:

After deliberation of the opposition division,

the chairman announced the following decision:

"The European patent is revoked."

Regarding the reasons for the decision, the chairman referred to:

Article 102(1) EPC: the following ground(s) for opposition mentioned in Article 100 EPC prejudice(s) the maintenance of the patent as granted.

Extension of subject-matter beyond content of the application as filed (Art. 123(2) EPC) Lack of Novelty (Art. 54(3) EPC)

The party/parties was/were informed that the minutes of the oral proceedings and a written reasoned decision (including an indication of the possibility of appeal) will be notified to him/them as soon as possible.

The chairman closed the oral proceedings on 21.11.2003 at 17.00 hours.

Chairman

Annex(es):
Auxiliary Request 1



Bescheid/Protokoll (Anlage)

Communication/Minutes (Annax)

Notification/Procès-verbal (Annexe)

Datum Date

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Demande n°:

Application No.: 97 904 958.2

- Both parties confirmed their requests as brought forward in the written procedure, according to which the opponent requested revocation of the granted patent in its entirety. The proprietor requested rejection of the opposition and maintenance of the patent in its granted form.
- 2 The representative of the proprietor cast doubt on the right of the representative of the opponent to grant sub-authorisations. He referred to the decision T0314/99 and to the EPO Official Journal 1991, 489. In the submission dated 21.10.2003 the representative of the opponent had sub-authorised A. Waugh to act as an additional representative, according to Article 134(7) EPC. The representative of the opponent stated that he had the right to grant sub-authorisations, that he had done so at an adequate time and that A. Waugh was an legally qualified representative.
- After a break for deliberation, the chairman announced the opinion of the division, 3 according to which the representative of the opponent was entitled to grant subauthorisations and according to which A. Waugh was entitled to attend the Oral Proceedings.
- The chairman opened the discussion with respect to added subject matter and 4 presented the preliminary opinion of the opposition division whereby the deletion of Figures 12a-c and 12h-i during the examination procedure did not extend the content of the application as filed. He asked the opponent for additional comments concerning why, in his view, subject-matter has been added.
- 5 The arguments presented by the opponent in his oral submissions, may be summarized as follows:
 - (i) In the application as originally filed, the longitudinal struts were defined as "disposed substantially parallel to the longitudinal axis of the stent". The deletion from claim 1 of this definition during the examination procedure extends the content of the application beyond that as originally filed, as s strut could be "longitudinal" without being "disposed substantially parallel to the longitudinal axis".



Bescheld/Protokoll (Anlage)

Communication/Minutes (Annex)

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Anmetde-Nr.: Demande n°:

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- (ii) The expression "in spaced relation" was introduced during the examination procedure. The introduction of the feature found basis solely in the Figures, in particular Figures 8-10 and 12d-g, where, however only flexure means being connected to the adjacent rows by two straight sections of the strut were disclosed. As a consequence, the wording of claim 1 covers arrangements that were not disclosed in the specification as originally filed, adding subject matter to the claim, contrary to Article 123(2) EPC.
- (iii) The term "arcuate" was introduced in the description and into the claims during prosecution of the file. The forms of flexure means that were disclosed in the application as filed were sinusoidal, S-shaped or bowed. As "arcuate" has a broader definition, comparable to "curved", as was acknowlegedby the patentee, the introduction of the word extends the subject matter of the patent beyond the content of the application as filed.
- (iv) The deletion of Figures 12a-c and 12h-i lead to a restriction to arcuate flexure means, whereby according to the application as filed, the shape of the flexure means had no effect on the alleged invention. The deletion of the non-curved flexure means suggested that the arcuate shape of the flexure means makes a contribution to the technical effect, which had not been noticed in the application as filed, and thus adds subject matter contrary to Article 123(2) EPC.
- 6 The chairman asked the proprietor to present his arguments. The proprietor denied that the above mentioned amendments resulted in an unallowable generalisation.
- 7 After a break for deliberation, the chairman announced the decision of the opposition division, according to which the subject-matter of claim 1 as granted contained added subject matter due to the insertion of "in spaced relation" and due to the deletion of "disposed substantially parallel to the longitudinal axis of the stent".

The chairman asked the proprietor if he wishes to file a new request. The opponent objected that a new request should not be admissible and referred to Rule 71a EPC. The proprietor alluded to the usual practice to allow late filed requests, particularly with regard to preliminary opinion of the opposition division which had been fully favourable.



Bescheid/Protokoll (Anlage)

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Anmelde-Nr.: Application No.: 97 904 958.2 Demands n°:

- After a short break, the proprietor presented a new set of claims 1-15. The chairman stated that claim 1 in the amended form was prima facie allowable. The chairman interrupted the Oral Proceedings according to the request of the opponent in order to allow him time to study the request and prepare a response.
- After reopening of the procedure, the chairman asked the opponent to present his objections. The opponent mentioned lack of novelty in view of document D1.
- The proprietor claimed that the priority of D1 was not valid as D9 was presumably not the first application. The chairman asked him for evidence, but the proprietor denied that he had the burden of proof. The opponent referred to the submissions filed with the letter dated 16.04.2003, wherein the point had already been debated under point B.3. The chairman indicated his view that the case was similar to the case discussed in the Guidelines, referring to formal requirements not met but leading to the findings that the priority was nevertheless considered valid for reasons of legal certainty. The patentee objected that the passage of the Guidelines referred to a translation not being filed for an Article 54(3) document but did not adress the case of a CIP.
- The opponent was requested to present his observations concerning the lack of novelty in the light of document D1. The arguments of the opponent were the following:
 - (i) The stent as disclosed on Fig. 7a is, contrary to the argumentation of the proprietor in his letter dated 02.12.2002, in an unexpanded state. He referred to several passages in the description to corroborate this statement.
 - (ii) Even if the stent as disclosed on Fig. 7a was already in an expanded state, the flexure means as shown in Fig. 7b or 7c would also be "arcuate" in the unexpanded state.
 - (iii) The "straight sections" preceeding the flexure means are known from D1, Fig. 7b and the flexure means shown are additionally curved, which, according to the proprietors argumentation, means that they are "arcuate".
- 12 The proprietor retorted the following:
 - (i) The stent as disclosed in D1 is directed to a stent which conforms, when expanded, to a vessel which is not straight, thus Fig. 7a shows a stent which has



Bescheld/Protokoli (Anlage)

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Anmelde-Nr.:
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Demande n':

been deployed.

- (ii) A shrinking of the flexure means ex posto is in his view artificial. He also indicated at this stage that he whished Mr. Ricci (the inventor) to be heard. The chairman refused and referred to decision G4/95.
- (iii) He denied that the flexure means as shown in Fig. 7b comprise a "curved" or "arcuate" middle section. He explained that a "curve" would be defined by "not causing trauma to the surrounding tissue".

Furthermore, he pointed out, that the row of intersecting members in D1 was different to those of the granted patent and that the flexure means as shown in Fig. 7c lacked a porous surface.

- After a break for deliberation the chairman stated that the priority of document D1 is valid, as the relevant Figures 7a-g are not disclosed in the earlier application 60/008254. During the break, the opponent had made a copy of the document 60/008254 available to the proprietor and to the opposition division.
- The chairman also announced the decision:
 The main request is rejected on the grounds of Article 123(2) EPC.
 The auxiliary request is rejected because claim 1 lacks novelty in view of document D1 (Article 54(3) EPC).

The European patent is revoked in its entirety.

NEW CLAIM 1

An unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of rows of intersecting members (750, 760, 850, 860, 950, 960), adjacent rows of intersecting members being interconnected by a series of longitudinal struts substantially parallel to the longitudinal axis (735, 740, 770, 835, 840, 870, 935, 940, 970), the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent;

characterised in that each longitudinal strut (735, 740, 770, 835, 840, 870, 935, 940, 970) comprises an arcuate flexure means (736, 741, 771, 836, 841, 936, 941, 971) disposed in the longitudinal strut between a first straight section and a second straight section in spaced relation between adjacent rows of intersecting members (750, 760, 850, 860, 950, 960) to allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts (735, 740, 770, 835, 840, 870, 935, 940, 970) upon flexure of the stent.

CLAIM 10 - DELETED.

20 CLAIMS 11-16 (AND DEPENDENCIES) RENUMBERED ACCORDINGLY.

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